



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0388; FRL-9346-6]

Dimethomorph; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerances for residues of dimethomorph, (*E,Z*)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or certain commodities as discussed in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0388. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>,

or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-9096; email address: *gibson.tamue@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to

a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0388 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0388, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7800) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that EPA amend 40 CFR part 180 by raising tolerances for residues of the fungicide dimethomorph, in or on brassica, head and stem, subgroup 5A from 2.0 ppm to 5.0 ppm; brassica, leafy greens, subgroup 5B from 20.0 ppm to 30.0 ppm; green onion, subgroup 3B from 2.0 ppm to 11.0 ppm. The petition also requested that 40 CFR part 180 be amended by establishing a tolerance for the residues of the fungicide dimethomorph, in or on vegetable, leafy at 16 ppm (PP 0F7816). The notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in

the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of October 27, 2010 (75 FR 66092) (FRL-8848-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7751) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that EPA establish a tolerance for residues of the fungicide dimethomorph, in or on grape at 3.5 ppm. The notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the proposed tolerance level and commodity definition for vegetable, bulb, group 3 and removed the established tolerance for the regional registration for grape. Tolerances for the national registration for grape and onion, bulb subgroup 3-07A were lowered. Tolerances for brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; vegetable, leafy except brassica, group 4; onion, green, subgroup 3-07B were raised. Tolerances for grape, raisin were established for domestic registrations and were also raised. EPA is also establishing rotational crop tolerances for wheat, forage; wheat, hay; and wheat, straw. EPA has made various changes to the commodity definitions and tolerance levels sought in the petition and also is establishing rotational crop tolerances. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dimethomorph including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dimethomorph follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Dimethomorph has low acute toxicity via the oral and dermal routes of exposure. Chronic risk is regulated based on effects seen in body weight decrements and liver effects in the female rat. There was no evidence of increased incidence of any neoplasms at the limit dose tested in carcinogenicity studies tested in rats and mice. Dimethomorph is classified as “not likely” to be a human carcinogen based on the lack of evidence of carcinogenicity in carcinogenicity studies in rats and mice. The available data for dimethomorph does not show evidence of neurotoxicity. There is a subchronic neurotoxicity study available which demonstrated no neurotoxic effects in the study. In addition, neither the subchronic nor chronic toxicity studies in rats or dogs, nor the developmental toxicity studies indicated that the nervous system was affected by treatment with dimethomorph.

Specific information on the studies received and the nature of the adverse effects caused by dimethomorph as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Dimethomorph: Human Health Risk Assessment to Support Amended Use on Grapes, Bulb Vegetables, Leafy *Brassica* Vegetables, and Leafy Vegetables,” pp. 35-38 in docket ID number EPA-HQ-OPP-2011-0388.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the

NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for dimethomorph used for human risk assessment is shown in the Table this unit.

Table —Summary of Toxicological Doses and Endpoints for Dimethomorph for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	No endpoint attributable to a single dose was identified.	Not applicable.	No study selected.
Acute dietary (General population including infants and children)	No endpoint attributable to a single dose was identified	Not applicable.	No study selected.
Chronic dietary (All populations)	NOAEL= 11 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day cPAD = 0.1 mg/kg/day	Carcinogenicity study in rats LOAEL = 46.3 mg/kg/day based on decreased body weight and increases in liver lesions in female rats.
Cancer (Oral, dermal, inhalation)	Classification: “Not likely to be Carcinogenic to Humans”		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality

Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. mg/kg/day = milligram/kilogram/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dimethomorph, EPA considered exposure under the petitioned-for tolerances as well as all existing dimethomorph tolerances in 40 CFR 180.493. EPA assessed dietary exposures from dimethomorph in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No toxic effects attributable to a single dose were observed in the toxicological studies for dimethomorph; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT). Dietary Evaluation Exposure Model (DEEM) default processing factors were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., dimethomorph has been classified as “not likely” to be a human carcinogen. EPA has concluded that dimethomorph does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue and PCT information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for dimethomorph. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dimethomorph in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dimethomorph. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of dimethomorph for acute exposures are estimated to be 81.1 parts per billion (ppb) for surface water and 0.264 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 24.7 ppb for surface water and 0.264 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value 24.7 ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dimethomorph is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found dimethomorph to share a common mechanism of toxicity with any other substances, and dimethomorph does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dimethomorph does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The available data did not provide evidence of any increased susceptibility in the offspring in either of the two developmental toxicity studies

or in the 2-generation reproduction study. In either of these two studies toxicity was not seen in the offspring occurring at doses lower than in the parent in any of the studies. Additionally, the effects seen in the young were qualitatively similar to those in the parents.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for dimethomorph is complete.
- ii. There is no indication that dimethomorph is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that dimethomorph results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The unrefined chronic dietary risk assessment used tolerance level residues, included modeled drinking water estimates, assumed 100 PCT, and incorporated DEEM default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dimethomorph in drinking water. These assessments will not underestimate the exposure and risks posed by dimethomorph.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected.

Therefore, dimethomorph is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dimethomorph from food and water will utilize 27% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for dimethomorph and thus residential exposure to residues of dimethomorph is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethomorph is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to dimethomorph through food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethomorph is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to dimethomorph through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dimethomorph is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to dimethomorph residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

FAMS-002-04 which utilizes high pressure liquid chromatography with ultraviolet detection (HPLC/UV) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for dimethomorph in or on grape at 2 ppm; and grape, raisin at 5 ppm. These MRLs are different than the tolerances being established for dimethomorph in this action because the MRLs are based on residue data derived from Europe.

C. Response to Comments

One comment was received from a private citizen (in reference to tolerance petition 0F7751) who encouraged the Agency to continue to reduce the risk to human health and the environment from pesticide usage. The Agency recognizes that some individuals believe that pesticide use should not be permitted. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

D. Revisions to Petitioned-For Tolerances

The crop group regulations (40 CFR 180.41) were recently amended pertaining to Crop Group 3 – Bulb Vegetables, and the revised Crop group is designated Crop group 3-07 Bulb Vegetable. The revised crop group now contains two subgroups: Bulb, subgroup 3-07A and onion, green, subgroup 3-07B. Because BASF proposed to modify its existing Crop Group 3 tolerance by adding a revised green onion tolerance, EPA has determined it is appropriate to establish both onion, bulb subgroup 3-07A and onion, green, subgroup 3-07B tolerances rather than a Crop Group 3 tolerance and a green onion tolerance. Based on

analysis of residue levels from crop field trial data and tolerance calculation procedures, EPA is setting the onion, bulb subgroup 3-07A tolerance at 0.6 ppm and the onion, green, subgroup 3-07B tolerance at 15 ppm. EPA is removing the existing Crop Group 3 tolerance.

Additionally, based on analysis of residue levels from crop field trial data and tolerance calculation procedures, EPA is raising tolerance levels for grape, raisin; brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; and vegetable, leafy, except brassica, group 4. For the same reason, EPA is lowering the tolerance for grape. Additionally, because the Agency is amending the BASF registration to allow use on grapes in the U.S., EPA is removing the footnote in the tolerance stating that such a registration does not exist.

Subsequent to the filing of the petition, the petitioner requested that the Agency establish tolerances in cereal grain commodities (forage, hay and straw) that are rotated to fields following use dimethomorph on commodities covered by the tolerances established in this action. The Agency determined that rotated crop tolerances would be appropriate for wheat, forage; wheat, hay; and wheat, straw.

V. Conclusion

Therefore, amended tolerances are established for residues of dimethomorph, in or on brassica, head and stem, subgroup 5A at 6.0 ppm; brassica, leafy greens, subgroup 5B at 30.0 ppm; onion, bulb subgroup 3-07A at 0.6 ppm; onion, green, subgroup 3-07B at 15.0 ppm; grape at 3.0 ppm; and grape, raisin at 7.0 ppm. A tolerance is established for residues of dimethomorph, in or on vegetable, leafy except brassica, group 4 at 30.0 ppm. This regulation also establishes tolerances for the indirect or inadvertent residues of dimethomorph, in or on wheat, forage at 0.15 ppm; wheat hay at 0.15 ppm and wheat, straw at 0.4 ppm. Furthermore,

this regulation removes established tolerances on vegetable, bulb, group 3 and footnote pertaining the lack of a registration for use on grapes.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA

section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 25, 2012.

Daniel J. Rosenblatt, Acting

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.493 is amended as follows:

- i. Remove the entry for “Vegetable, bulb, group 3”; and footnote 1 from the table in paragraph (a);
- ii. By revising the entries for “Brassica, head and stem, subgroup 5A,” “Brassica, leafy greens, subgroup 5B” and “Grape, raisin” and alphabetically adding new entries to the table in paragraph (a);
- iii. Remove “Grape” from the table in paragraph (c);
- iv. Revise paragraph (d) .

The amendments read as follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) * * *

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	6.0
Brassica, leafy greens, subgroup 5B	30.0
* * * * *	
Grape	3.0
Grape, raisin	7.0
* * * * *	
Onion, bulb, subgroup 3-07A	0.6
Onion, green, subgroup 3-07B	15.0
* * * * *	
Vegetable, leafy (except Brassica) group 4	30.0

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide dimethomorph, in or on the commodities in the following table. Compliance with the following tolerance levels specified in the following table is to be determined by measuring only dimethomorph (*E,Z*)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine calculated in or on the following commodities:

Commodity	Parts per million
Wheat, forage	0.15
Wheat, hay	0.15
Wheat, straw	0.4

[FR Doc. 2012-10709 Filed 05/03/2012 at 8:45 am; Publication Date: 05/04/2012]